

### **REMARKS**

This paper is presented in response to the non-final official action of September 5, 2007, wherein (a) claims 1 and 8-16 were pending, (b) Groups I and II of the restriction requirement rejoined, but the restriction of Groups III-IX was maintained and made final, (c) the inventors' declaration was objected to, (d) the claims and specification were objected to as not conforming to sequence rules as laid out in 37 C.F.R. §§1.1821-1.825, (e) claims 1 and 8-12 were objected to for containing the terms "this nucleic acids" or "less nucleotides," (f) the specification was further objected to for failure to include a "Brief Description of the Drawings" section, (g) claim 13 was rejected under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite, (h) claims 1, 8-12, and 14-16 were rejected under 35 USC 1<sup>st</sup> paragraph as failing to comply with the written description requirement, and (i) claims 1 and 8-15 were rejected under 35 USC 101 as being directed to non-statutory subject matter.

This response is timely-filed, as it is accompanied by a petition for automatic extension of time to file in the third month, and the requisite petition fee.

Reconsideration of the application, as amended, is solicited.

#### **I. AMENDMENTS TO THE SPECIFICATION AND CLAIMS**

The specification has been amended to correctly refer to sequences as required under 37 C.F.R. §§1.821-1.825 and to correct the typographical error in the abstract. Claims have been amended to correct typographical errors and recite the elected sequences of Group I and Group II. Specifically, claim 1 has been amended (1) to recite one nucleic acid sequence from the elected group due to the restriction requirement; (2) to recite that the nucleic acid is isolated as suggested by the

examiner; and (3) to specify that the recited nucleic acid has a sequence having at least 90% identity to SEQ ID NO: 1 or SEQ ID NO: 2.

Claim 8 has been amended to recite that the claimed nucleic acid is isolated, as suggested by the examiner and to recite that the sequence has at least 95% identity to SEQ ID NO: 1 or SEQ ID NO: 2.

Claims 9-12 have been amended to recite that the claimed nucleic acid is isolated, as suggested by the Patent Office and that the anti-apoptotic activity is at least 70%, at least 80%, at least 90%, or at least 95% inhibition, respectively.

Claims 13-16 have been amended to correct typographical errors and to recite that the claimed nucleic acid is isolated, as suggested by the examiner. Support for these amendments can be found in the specification at p. 5, lines 1-11.

No new matter is submitted with these amendments.

## **II. REQUIREMENT FOR A NEW OATH OR DECLARATION**

An English language declaration was electronically submitted on November 1, 2007, as required by the official action dated September 5, 2007.

## **III. THE OBJECTION TO THE SPECIFICATION SHOULD BE WITHDRAWN**

### **A. Sequence Compliance**

Amendments to the specification and claims are submitted herewith to correct the sequence identifiers to comply with the rules under 37 C.F.R. §§1.821-1.825. Also submitted herewith is a substitute sequence listing to include a sequence which was inadvertently omitted. The sequence recited on page 8, line 24, has been labeled as SEQ ID NO: 10 and is included in the sequence listing provided herewith. No new matter is introduced with this substitute sequence listing.

**B. Abstract and Brief Description of the Drawings**

The abstract has been amended as suggested by the examiner to remove a second period after the first sentence of the abstract.

In the Preliminary Amendment, submitted June 2, 2006, the specification was amended to include a heading "BRIEF DESCRIPTION OF THE DRAWINGS" on page 8, after line 22. The "Brief Description of the Drawings" section on page 8, line 22 to page 9, line 5 refers to and identifies the sequences shown in the drawing figures by their SEQ ID NO. Therefore, the examiner's suggestion to amend the specification to include a "Brief Description of the Drawings" and refer to the sequences shown therein was previously addressed. It is therefore submitted that the objection to the specification is moot and should be withdrawn.

**IV. OBJECTION TO AND REJECTION OF THE CLAIMS**

**A. Objections to the Claims**

Claims 1 and 8-12 are objected to for use of "this nucleic acids." With this amendment, claims 1 and 8-12 have been amended accordingly, so this objection is moot and should be withdrawn.

Claims 8-12 are objected to for use of the phrase "less nucleotides." With this amendment, claims 8-12 have been amended accordingly, so this objection is moot and should be withdrawn.

**B. Rejection of Claim 13 under 35 U.S.C. §112, Second Paragraph**

Claim 13 stands rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the examiner identifies the phrase "selected from those." With this amendment, claim 13 has been amended to properly recite the Markush group of claimed nucleic acid sequences. It is submitted that this rejection is moot and should be withdrawn.

**C. Rejection of Claims 1, 8-12, and 14-16 under 35 U.S.C. §112, First Paragraph**

Claims 1, 8-12, and 14-16 stand rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. With this amendment, claim 1 has been amended to delete the term “functional variant” and recite the feature that the claimed isolated nucleic acid has a sequence with at least 90% identity to SEQ ID NO: 1 or SEQ ID NO: 2. It is submitted that amended claims 1, 8-12, and 14-16 are each supported by an adequate written description in the application as filed. These claims are directed to polynucleotide sequences that are at least 90% identical to SEQ ID NO: 1 or 2 and that have anti-apoptotic activity. The structural and functional limitations recited in claims 1, 8-12, and 14-16 meet the Written Description Guidelines of the United States Patent and Trademark Office, 66 Fed. Reg. 1099 (January 30, 2001). In particular, Example 16 of the Revised Interim Written Description Guidelines Training Materials states that the Guidelines “indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus.” (66 Fed. Reg. 1099, 1102.) Additionally, Example 14 of the Revised Interim Written Description Guidelines Training Materials is consistent with those guidelines and teaches that a claimed variant polynucleotide that is substantially similar to a sequence taught in the specification, along with a functional limitation that the claimed variant polynucleotide encodes a variant polypeptide that exhibits an identified activity, meets the written description requirement if the required activity can be determined from the specification. In the instant case, the claimed variants have sequences that are at least 90% identical to SEQ ID NOS: 1 or 2 and therefore do not have substantial variation from the sequences taught in the specification. In addition, the claimed variants are limited to those that retain anti-apoptotic activity. Accordingly, the structural and functional limitations of claims 1, 8-12, and 14-16 are described in the specification in such a way as to convey to one of skill in the art that the applicants had possession of the claimed invention at the time of filing the application. It is submitted that this rejection should be withdrawn.

**D. Rejection of Claims 1 and 8-15 under 35 U.S.C. §101**

Claims 1 and 8-15 stand rejected under 35 U.S.C. §101 for allegedly claiming non-patentable subject matter. With the amendment to claims 1 and 8-15 submitted herewith to recite an *isolated* nucleic acid, it is submitted that this rejection is moot and should be withdrawn.

**V. CONCLUSION**

In view of the above amendments and remarks, the applicants believe the pending application is in condition for allowance.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, he is urged to telephone the undersigned at the indicated number.

February 29, 2008

Respectfully submitted,

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